

OncoSpan FFPE DNA Reference Standard

PRODUCT INFORMATION

Catalog ID	HD832
Batch ID	40763
Product Description	OncoSpan FFPE Reference Standard Set
Date of Manufacture	21-Aug-2019
Manufacturing QMS Status	ISO 13485

PROPERTIES

Format	15 µm section
Storage Conditions	+4°C (2-8°C)
Use by	For the latest information on product shelf life, please visit our website: https://horizondiscovery.com/products/diagnostic-reference-standards/reference-standards-product-information

CUSTOMER SUPPORT

Technical Support	technical@horizondiscovery.com
Customer Service	orders@horizondiscovery.com

ADDITIONAL INFORMATION

N/A

Horizon Discovery

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QUALITY CONTROL

 Allele Frequency (AF) and Genotype: **Droplet Digital™ PCR**

Gene	Variant	Expected AF (%)	Actual AF (%)	Acceptance Criteria (%)		Pass/Fail
				Low	High	
BRAF	V600E	10.70	12.13	7.49	13.91	PASS
KIT	D816V	10.00	8.95	8.00	12.00	PASS
EGFR	ΔE746-A750	1.90	1.70	1.30	2.50	PASS
EGFR	p.L858R	2.80	3.66	1.68	3.92	PASS
EGFR	p.T790M	0.90	1.06	0.60	1.20	PASS
EGFR	p.G719S	24.50	24.49	22.10	27.00	PASS
KRAS	p.G13D	15.00	13.91	12.00	18.00	PASS
KRAS	p.G12D	6.30	7.52	5.00	7.60	PASS
NRAS	Q61K	12.50	12.26	10.00	15.00	PASS
PIK3CA	p.H1047R	17.50	17.77	14.00	21.00	PASS
PIK3CA	p.E545K	8.80	8.32	7.00	10.60	PASS

 Allele Frequency (AF) and Genotype: **Droplet Digital™ PCR** (additional variants detected for information only)

Gene	Variant	Expected AF (%)	Actual AF (%)
ALK	3'_UTR_insertion	10.00	9.22
APC	P.T1493T	35.00	35.8
BRCA2	p.K1691fs*15	32.50	32.50
CTNNB1	p.S33Y	32.50	31.60
CTNNB1	p.S45del	10.00	8.76
EGFR	p.Q787Q	15.00	13.25
FBXW7	p.S668fs*39	32.50	32.10
FLT3	p.P986fs*>8	10.00	8.96
KIT	p.L862L	7.50	8.27
MET	p.A1357A	7.00	6.16
MET	p.L238fs*25	7.00	6.27
NOTCH1	p.P668S	30.00	30.3
RET	p.L769L	60.00	62.2
TP53	p.P72R	92.50	91.73

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Quality: Agarose gel electrophoresis		
Acceptance Criteria	Band Present/Absent	Pass/Fail
Bright band of high molecular weight	Present	PASS
Quantification: QuantiFluor® assay (Promega) *		
Acceptance Criteria	Reading	Pass/Fail
≥ 400 ng (Average yield)	618.47 ng	PASS

*DNA extraction performed using Maxwell® 16 FFPE plus LEV DNA Purification Kit (Promega)

FOR RESEARCH USE ONLY

Manufactured in the UK